



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/698,341	10/27/2000	Joseph A. Sorge	25436/1560	6038

27495 7590 10/17/2003
PALMER & DODGE, LLP
KATHLEEN M. WILLIAMS / STR
111 HUNTINGTON AVENUE
BOSTON, MA 02199

EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
----------	--------------

1652

27

DATE MAILED: 10/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/698,341

Applicant(s)

SORGE ET AL.

Examiner

Richard G Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5 and 89-127 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,5,90-92,108,109,115-121,126 and 127 is/are allowed.
- 6) ☐ Claim(s) 89,91,93-107,110,113,114 and 122-125 is/are rejected.
- 7) ☒ Claim(s) 111 and 112 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 22.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment of the specification, cancellation of claims 2, 3, 6-10, 12-47, 85-88 and addition of new claims 89-127, Paper No. 23, 7/25/2003, is acknowledged. Claims 1, 5 and 89-127 are at issue and present for examination. Applicants' arguments filed on 7/25/2003, Paper No. 23, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

The disclosure is objected to because of the following informalities:

Figures 14 and 15 each comprise a number of sequences but there is no indication in the figure or the description of the figure as to the associated SEQ ID NOs.

As per MPEP Section **2422.02**, *The Requirement for Exclusive Conformance;*

Sequences Presented

in Drawing Figures, it should be noted, though, that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings.

In response to this previous objection applicants have stated that this was corrected in a previous amendment, a copy of which was supplied along with the

Art Unit: 1652

previous action, however the referred to amendment could not be found, thus the objection is maintained.

Appropriate correction is required.

Claim Objections

Claims 89-92, 99, 104, 111, 112, 114, 117-121 are objected to because of the following informalities:

Claim 92 recites "...and praline (P) to leucine (L)." This should be "...and proline (P) to leucine (L).

Claims 89-92, 99 and 104 recite "...one or more amino acids in exo I (DXE) motif..." It is suggested that this be amended to "...one or more amino acids in the or a exo I (DXE) motif..." depending on applicants intent with respect to exo I motif.

Claims 96, 97, 100, 101, 102 and 105 are similarly objected to for the same reason as claims 89-92, 99 and 104 directly above, with respect to **the/a** exo II or exo III motifs.

In order to avoid any confusion and for clarity sake, it is suggested that claim 111 be amended from "...wherein said mutation at one or more amino acids is at L408 or P410 within Region II" to "...wherein said mutation at one or more amino acids of **Region II** is at L408 or P410".

Claim 114 recites "isolated recombinant LDF-3 DNA polymerase". This should be "isolated recombinant JDF-3 DNA polymerase".

Claims 117-121 each recite "within said sequence ID NO: 2". This should be "within SEQ ID NO: 2".

Claims 111 and 112 are dependent on rejected claim 110.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 89-107, 113, 114 and 122-125 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 89-107 (claims 122-125 dependent on) are indefinite in that the recitation "exo I (DXE) motif" is confusing and unclear. Claim 89 is drawn to a polymerase comprising a sequence of SEQ ID NO: 2 and further comprising a mutation at one or more amino acids in exo I (DXE) motif within said sequence of SEQ ID NO: 2. Specifically it is unclear what is encompassed by applicants recitation "exo I (DXE) motif". Since SEQ ID NO: 2 comprises five different "DXE" motifs, and applicants have only introduced mutations in one of these "DXE" motifs, it would appear that applicants intend for some additional characteristics to define the recited "exo I motif" beyond the mere amino acid sequence "DXE" however it is unclear what these additional characteristics are. Further, claims 96, 97, 100, 102 and 105, are similarly confusing

Art Unit: 1652

and unclear in the recitations "exo II (NX2-3FD) motif" and "exo III (YX₃D) motif". It is noted that the exo III motif "YX₃D" occurs in at least three different places in SEQ ID NO: 2. For the purpose of advancing prosecution the exo I (DXE) motif is interpreted as occurring at amino acid positions 141-143 of SEQ ID NO: 2, while the exo II (NX2-3FD) motif and "exo III (YX₃D) motif" are interpreted as those motifs occurring at positions 210 through 215 and positions 311 through 315, respectively, of SEQ ID NO: 2.

Claims 99-107 are indefinite in that each of these claims are drawn to a recombinant family B DNA polymerase comprising a sequence selected from those accession numbers listed in Table II. These claims are indefinite because accession numbers as listed in Table II are subject to change and thus any limitation dependent on such an accession number is subject to change and thus vague, confusing and unclear.

Claims 93, 94, 113 and 114 each refer to "Y490" of SEQ ID NO: 2. Position 490 of SEQ ID NO: 2 is an alanine residue, not a tyrosine residue.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 89, 91, 93-107 and 122-125 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Newly added claims 89, 91, 93-107 and 122-125 are rejected under this statute because the newly added subject matter of these claims is not supported by the original specification. Specifically, the recitation in claim 89, "further comprising a mutation at one or more amino acids in exo I (DXE) within" is not supported by the original specification. Applicants amendment on page 56 to incorporate the structures of the exo motifs as taught by Derbyshire V et al. and applicants comments stating "no new matter is added" are acknowledged. While it is acknowledged that applicants have support for the "replacement of any of the conserved aspartic or glutamic acid residues with alanine..." as a means of abolishing the exonuclease activity of numerous DNA polymerases, applicants do not have support for the replacement of any of the exo motif residues other than aspartic or glutamic acid residues (i.e. the "X" residue).

Newly added claims 91, 93, 97, 98, 101, 102 and 110 are rejected under this statute because as discussed above for claims 89, 91, 93-107 and 122-125, additional newly added subject matter of these claims is not supported by the original specification. Specifically, the recitation in claim, "and a mutation at one or more amino acids in Region II (DXXSLYPSII) within.." is not supported by the original specification. While it is acknowledged that applicants have support for the "replacement of specific amino acid positions within Region II, applicants do not have support for the mutation of any and all amino acid positions in Region II.

Newly added claim 93 (claim 94 dependent on) is further rejected under this statute because the recitation "Y490" is not supported by the original specification.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a stylized, cursive script.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rg
10/16/2003